FEB 1 6 2001

K003130

510(k) Summary

1. GENERAL INFORMATION

Submitter: SIE-MED Incorporated
101 Le Goult Drive
Cary, NC 27513

Contact Person: Mr. Karl Harbauer

Date of 510(k) Summary Preparation: September 19, 2000

Name of Device: REGUTHERM 952

2. PREDICATE DEVICES

- Werner Eidam Medizin-Technologie GmbH – CRT 2000 Thermography System (K971956)
- Ashwin Systems International, Inc. – Teletherm Mark-1026 (K863818)
- Bales Scientific, Inc. – Thermal Image Processor (K897191)

3. DEVICE DESCRIPTION

Similar to the cited predicate devices, the REGUTHERM 952 is an adjunctive diagnostic thermographic system that measures the temperature of the skin surface. A temperature probe is manually moved to different locations on the patient's body. A computer processor provides a visual display of the temperature readings and compares the readings for a body location at several points in time.

4. INTENDED USE

The REGUTHERM 952 is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis of (1) abnormalities of the female breast; (2) peripheral vascular disease; (3) musculoskeletal disorders; (4) extracranial cerebral and facial vascular disease; (5) abnormalities of the thyroid gland; and (6) various neoplastic and inflammatory conditions. Use of the REGUTHERM 952 is not intended to be the sole diagnostic procedure for these diseases and conditions.

5. TECHNOLOGICAL CHARACTERISTICS

Similar to the predicate devices the REGUTHERM 952 is a sensitive skin temperature measuring system that utilizes a computer analysis system. Similar to the CRT 2000 Thermography System it uses a direct contact method for measuring skin temperature rather than infrared radiation detection used by the other cited predicate devices to which FDA found the CRT 2000 to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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SIE-MED, Lnc.
C/O Charles Kyper
Kyper Associates
11902 Simpson Road
CLARKSVILLE MD 21029

Re: K003130
REGUTHERM 952 Thermographic system
Dated: December 30, 2000
Received: January 5, 2001
Regulatory Class: I
21 CFR §884.2980/Procode: 90 LHQ

Dear Mr. Kyper:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indication for Use

510(k) Number (if known): K003130

Device Name: REGUTHERM 952

Indication for Use: use as an adjunct to other clinical diagnostic procedures in the diagnosis of (1) abnormalities of the female breast, (2) peripheral vascular disease, (3) musculoskeletal disorders, (4) extracranial cerebral and facial vascular disease, (5) thyroid gland abnormalities, and (6) various neoplastic and inflammatory conditions. Use of the REGUTHERM 952 is not intended to be the sole diagnostic procedure for these diseases and conditions.

Concurrence of CDRH Office of Device Evaluation

Prescription Use / **(per 21 CFR 801.109)** **OR** **Over-the-counter Use** ____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003130